

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 17-1357V

Filed: October 27, 2022

PUBLISHED

TRACY MURRAY,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

Special Master Horner

Entitlement; shoulder injury
related to vaccine
administration ("SIRVA");
bursitis; influenza ("flu")
vaccine; cause-in-fact.

Leah VaSahnja Durant, Law Offices of Leah V. Durant, PLLC, Washington, DC, for petitioner.

Austin Joel Egan, U.S. Department of Justice, Washington, DC, for respondent.

RULING ON ENTITLEMENT¹

On September 27, 2017, petitioner Tracy Murray ("petitioner") filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10-34 (2012),² alleging that she suffered a shoulder injury related to vaccine administration ("SIRVA") as a result of the influenza ("flu") vaccine she received on October 12, 2016. (ECF No. 1.) Alternatively, if petitioner is unable to establish that she suffered a Table injury of SIRVA, she argues that her flu vaccine was the cause-in-fact of her shoulder injury. (ECF No. 53, p. 9.) For the reasons set forth below, I find that petitioner is entitled to an award of compensation for her shoulder injury, which was caused-in-fact by the flu vaccine.

¹ Because this ruling contains a reasoned explanation for the special master's action in this case, it will be posted on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. See 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the decision will be available to anyone with access to the Internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information the disclosure of which would constitute an unwarranted invasion of privacy. If the special master, upon review, agrees that the identified material fits within this definition, it will be redacted from public access.

² All references to "§ 300aa" below refer to the relevant section of the Vaccine Act at 42 U.S.C. § 300aa-10-34.

I. Applicable Statutory Scheme

Under the National Vaccine Injury Compensation Program, compensation awards are made to individuals who have suffered injuries after receiving vaccines. In general, to gain an award, a petitioner must make several factual demonstrations, including showing that an individual received a vaccination covered by the statute; received it in the United States; suffered a serious, long-standing injury; and has received no previous award or settlement on account of the injury. Finally – and the key question in most cases under the Program – the petitioner must also establish a causal link between the vaccination and the injury. In some cases, the petitioner may simply demonstrate the occurrence of what has been called a “Table Injury.” That is, petitioners may show that they suffered an injury of the type enumerated in the “Vaccine Injury Table,” corresponding to the vaccination in question, within an applicable time period following the vaccination also specified in the Table. In such cases, the Table Injury is presumed to have been caused by the vaccine. § 300aa-13(a)(1)(A); § 300 aa-11(c)(1)(C)(i); § 300aa-14(a); § 300aa-13(a)(1)(B).

As relevant here, the Vaccine Injury Table lists a shoulder injury related to vaccine administration, or “SIRVA” as a compensable injury if it occurs within 48 hours of administration of an influenza vaccine. §300aa-14(a) as amended by 42 CFR § 100.3. Table Injury cases are guided by a statutory “Qualifications and aids in interpretation” (“QAI”), which provides more detailed explanation of what should be considered when determining whether a petitioner has suffered an injury listed on the Vaccine Injury Table. (§300aa-14(a).) To be considered a Table “SIRVA” petitioner must show that her injury meets all of the following criteria:

- (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection; and
- (ii) Pain occurs within the specified time-frame; and
- (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
- (iv) No other condition or abnormality is present that would explain the patient’s symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. §100.3(c)(10).

Alternatively, if no injury falling within the Table can be shown, the petitioner may still demonstrate entitlement to an award by showing the vaccine recipient’s injury was “caused-in-fact” by the vaccine they received, a showing often referred to as “actual

causation.” § 300aa-13(a)(1)(B); § 300aa-11(c)(1)(C)(ii). In these “off-Table” cases, the presumptions available under the Vaccine Injury Table are inoperative, and the burden is on the petitioner to introduce evidence demonstrating that the vaccination was responsible for the injury in question. *Althen v. Sec’y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005); *Hines v. Sec’y of Health & Human Servs.*, 940 F.2d 1518, 1525 (Fed. Cir. 1991).

The showing of “causation-in-fact” must satisfy the “preponderance of the evidence” standard, the same standard ordinarily used in tort litigation. § 300aa-13(a)(1)(A); see also *Althen*, 418 F.3d at 1279; *Hines*, 940 F.2d at 1525. Under that standard, the petitioner must show that it is “more probable than not” that the vaccination was the cause of the injury. *Althen*, 418 F.3d at 1279. The petitioner need not show that the vaccination was the sole cause of the injury or condition, but must demonstrate that the vaccination was at least a “substantial factor” in causing the condition, and was a “but for” cause. *Shyface v. Sec’y of Health & Human Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999). Thus, the petitioner must supply “proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury;” the logical sequence must be supported by “reputable medical or scientific explanation, *i.e.*, evidence in the form of scientific studies or expert medical testimony.” *Althen*, 418 F.3d at 1278; *Grant v. Sec’y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). A petitioner may not receive a Vaccine Program award based solely on his or her assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. § 300aa-13(a)(1).

In what has become the predominant framing of this burden of proof, the *Althen* court described the “causation-in-fact” standard, as follows:

Concisely stated, *Althen*’s burden is to show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury. If *Althen* satisfies this burden, she is “entitled to recover unless the [government] shows, also by a preponderance of the evidence, that the injury was in fact caused by factors unrelated to the vaccine.”

Althen, 418 F.3d at 1278 (citations omitted). The *Althen* court noted that a petitioner need not necessarily supply evidence from medical literature supporting petitioner’s causation contention, so long as the petitioner supplies the medical opinion of an expert. *Id.* at 1279-80. That expert’s opinion must be based upon “sound and reliable” scientific explanation. *Boatmon v. Sec’y of Health & Human Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019) (quoting *Knudsen v. Sec’y of Health & Human Servs.*, 35 F.3d 543, 548-49 (Fed. Cir. 1994)). The *Althen* court also indicated that, in finding causation, a Program factfinder may rely upon “circumstantial evidence,” which the court found to be consistent with the “system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants.” 418 F.3d at 1280.

II. Procedural History

On September 27, 2017, petitioner filed her petition alleging that the flu vaccine she received on October 12, 2016, caused her to suffer a left SIRVA. (ECF No. 1.) The case was initially assigned to the Special Processing Unit (“SPU”). (ECF No. 5.) Petitioner filed medical records followed by a statement of completion on October 10, 2017. (ECF Nos. 7, 8.) She subsequently filed additional medical records, an affidavit, and her workers compensation records. (ECF Nos. 9, 11.)

Respondent filed his Rule 4(c) report recommending against compensation on August 3, 2018. (ECF No. 23.) Respondent argued that petitioner could not satisfy the elements necessary for a Table Injury of SIRVA because she had not established that the onset of her pain began within forty-eight hours of vaccination, that her pain was limited to her left shoulder, or that she had no preexisting shoulder injury. (*Id.*)

In response to respondent’s Rule 4(c) report, petitioner presented an expert report from orthopedic surgeon Clifford J. Colwell, Jr., M.D., on February 19, 2019. (ECF No. 27; Ex. 13.) On May 28, 2019, respondent offered a responsive expert report from orthopedic surgeon Brian Feeley, M.D. (ECF No. 30; Ex. A.) Petitioner then filed a supplemental report from Dr. Colwell on September 23, 2019. (ECF No. 36; Ex. 16.)

On December 13, 2019, Chief Special Master Corcoran held a status conference with the parties. (ECF No. 38.) During the conference, respondent’s counsel indicated that settlement was unlikely. (*Id.* at 1.) Chief Special Master Corcoran stated that if onset were the sole disputed issue, he might have credited Dr. Colwell’s report regarding the timing of petitioner’s pain following vaccination. (*Id.* at 2 (citing Ex. 16).) However, he noted that Dr. Feeley discussed potential alternative sources of petitioner’s pain based on her MRI. (*Id.*) Accordingly, Chief Special Master Corcoran concluded that the case was no longer appropriate for SPU. (*Id.*)

The case was subsequently reassigned to Special Master Roth, who ordered petitioner to file a supplemental expert report from Dr. Colwell. (ECF Nos. 40, 41.) Special Master Roth stated that the medical records indicate that petitioner complained of shoulder pain within forty-eight hours of vaccination after finishing a course of prednisone. (ECF No. 41, p. 2.) Special Master Roth instructed Dr. Colwell to prepare a supplemental report addressing the effect of prednisone on petitioner’s pain, the significance of her MRI findings, the role of the inflammatory process caused by petitioner’s allergic reaction to the flu shot, and the impact of petitioner’s distal clavicle excision to treat her arthritis. (*Id.*)

The parties continued the exchange of expert reports. Petitioner filed a supplemental report from Dr. Colwell on April 20, 2020. (ECF No. 42; Ex. 18.) On June 22, 2020, respondent filed a supplemental report from Dr. Feeley. (ECF No. 43; Ex. C.) Petitioner then filed a report from a new expert, orthopedic surgeon Uma Srikumaran, M.D., on October 21, 2020. (ECF No. 46; Ex. 19.) Dr. Feeley offered a report responding to Dr. Srikumaran on December 21, 2020. (ECF No. 47; Ex. D.)

This case was reassigned to my docket on January 26, 2021. (ECF No. 49.) Shortly after, the expert report stage concluded with a supplemental report from Dr. Srikumaran filed on February 4, 2021. (ECF No. 50; Ex. 30.) In a status conference held on March 31, 2021, I indicated that based on my understanding of the record, I did not feel a hearing was necessary. (ECF No. 51.) The parties expressed interest in resolving the case on the written record. (*Id.*)

On April 30, 2021, the parties confirmed that the case was ripe for an entitlement determination. (ECF No. 52.) The parties proposed that the case be resolved on the written record. (*Id.*) On June 17, 2021, petitioner filed her motion for a ruling on the written record and accompanying memorandum. (ECF No. 53.) Respondent filed his responsive memorandum on September 22, 2021. (ECF No. 56.) Petitioner filed a reply on November 8, 2021. (ECF No. 57.)

Special masters “must determine that the record is comprehensive and fully developed before ruling on the record.” *Kreizenbeck v. Sec’y of Health & Human Servs.*, 945 F.3d 1362, 1366 (Fed. Cir. 2020); *see also* Vaccine Rule 8(d); Vaccine Rule 3(b)(2). The parties must have a full and fair opportunity to present their case and develop a record sufficient for review. *Id.* In light of all of the above, and upon review of the entire record, I conclude that petitioner has had a full and fair opportunity to develop the record of this case and that the case is ripe for resolution on the existing record.

III. Factual History

a. As Reflected in the Medical Records

Petitioner was forty-six years old when she received the flu vaccine in her left deltoid on October 12, 2016.³ (Ex. 1.) The following day, on October 13, 2016, petitioner presented to Southern Main Health Care for a latex reaction from the flu vaccine. (Ex. 3, p. 11.) The nurse practitioner, Kristen Waitt (“Nurse Waitt”), noted that petitioner experienced near immediate severe itching and pain at the injection site. (*Id.*) Petitioner also reported that it felt like her throat was closing. (*Id.*) Nurse Waitt believed that petitioner was having a “[p]ost-immunization reaction” and administered 50 mg of diphenhydramine (Benadryl) to alleviate her symptoms. (*Id.*; *see also* Ex. 6, p. 2.) Nurse Waitt recommended petitioner go to the emergency room (“ER”) via ambulance. (Ex. 3, p. 11.)

Upon arrival to the Southern Maine Health Care ER, petitioner was examined by physician assistant (“PA”) Erica Chaffey. (Ex. 6, p. 2.) PA Chaffey’s examination revealed “[a] 5.5 cm x 6.5 cm macular erythematous avoid lesion with a smaller area of painless induration beneath.” (*Id.* at 3.) Petitioner was prescribed 60 mg of prednisone per day to treat her injury. (Ex. 7, p. 16.)

³ In fact, the vaccination record initially recorded administration in the right arm and was subsequently corrected to reflect a left arm administration. (Ex. 1.) Given the subsequent history, respondent agrees that the right arm notation was likely an error. (ECF No. 23, p. 2, n. 2.)

One week later, on October 20, 2016, petitioner returned to Southern Maine Health Care for evaluation by Paul Upham, M.D. (Ex. 6, p. 5.) Petitioner reported that she experienced some aching after a few days on prednisone, which had resolved by the time of her visit. (*Id.*) Petitioner again presented to Dr. Upham on October 26, 2016, reporting aching in her left shoulder over the last few days. (*Id.* at 8.) In addition to left shoulder pain, petitioner described “tingling which radiate[d] down the left arm into the hand.” (*Id.*) Upon examination, petitioner’s left shoulder had nearly full range of motion; however, petitioner complained of pain in the shoulder with movement. (*Id.* at 8-9.) Petitioner told Dr. Upham that her left shoulder began to throb and that the tingling worsened after Dr. Upham conducted his examination. (*Id.*) Dr. Upham concluded that petitioner had “[l]eft shoulder discomfort and left upper extremity tingling, likely musculoskeletal, question[able] cause.” (*Id.* at 9.)

Petitioner visited her primary care provider, family nurse practitioner Laura Hill (“Nurse Hill”), on October 27, 2016. (Ex. 2, p. 29.) Petitioner reported that she “developed left shoulder pain with sharp pain radiating down her arm and tingling in [her] hand” after completing her course of prednisone on October 19, 2016. (*Id.*) Nurse Hill assessed petitioner with “left arm pain.” (*Id.* at 31.)

On October 31, 2016, petitioner returned to Dr. Upham to follow up on her shoulder pain. (Ex. 6, p. 11.) Petitioner reported that her left shoulder pain had improved and was intermittent but that she still had soreness with movement. (*Id.*) Later that same day, petitioner presented to infectious disease specialist Thomas Courtney, M.D., with complaints of an “allergic reaction to [the] influenza vaccine.” (Ex. 2, p. 81.) Dr. Courtney noted, “Although the inflammation is resolved [petitioner] still has some ache in her upper left arm in [the] deltoid area she notices mostly with movement, but this is non limiting.” (*Id.*) Dr. Courtney assessed petitioner as suffering from an “[a]dverse reaction either hypersensitivity reaction or rigorous immune response from prior vaccination.” (*Id.*) He recommended that petitioner “avoid revaccination from injectable influenza vaccine from here on.” (*Id.*) He concluded that petitioner’s “[a]rm pain [was] probably residual soft tissue inflammation which should resolve in time.” (*Id.*)

Petitioner returned to Nurse Hill for complaints of “arm pain” on December 9, 2016. (Ex. 2, p. 33.) Petitioner reported that she had been experiencing constant left shoulder pain since she received the flu vaccine two months prior. (*Id.*) Petitioner described a grinding sensation and noted that she was experiencing numbness and weakness. (*Id.*) Although Nurse Hill recorded that petitioner’s shoulder pain was due to an unclear cause, her impression was that petitioner had left shoulder impingement or potential rotator cuff issues. (*Id.* at 35.) Nurse Hill directed petitioner to manage her pain with ibuprofen and referred her to an orthopedist. (*Id.*)

One week later, on December 16, 2016, petitioner saw PA Bronna Eckelman at Southern Maine Health Care. (Ex. 3, p. 8.) Petitioner reported that she had been experiencing shoulder pain for two months since her flu vaccine and described her pain level as an eight out of ten. (*Id.*) PA Eckelman examined petitioner’s left shoulder and noted the flexion was “150 degrees with discomfort at end range, internal rotation to

lower lumbar level compared to upper thoracic.” (*Id.*) PA Eckelman also observed “[m]ild tenderness at the A/C [acromioclavicular] joint, mild tenderness at the supraspinatus and infraspinatus fossa, [and] tender[ness] across the trapezius.” (*Id.* at 9.) Petitioner had a negative acromioclavicular (“AC”) joint crossover test, positive Neer’s sign, and a positive Hawkins test. (*Id.*) PA Eckelman concluded that petitioner “appears to have an inflammatory condition in the shoulder, potentially brought on after an allergic reaction to the flu shot. She may also have a cervical radiculitis.” (*Id.*) PA Eckelman also assessed petitioner with osteoarthritis of the AC joint. (*Id.*)

Petitioner underwent a left shoulder MRI on December 21, 2016. (Ex. 3, p. 18.) The MRI revealed “degeneration and tearing of the anterior labrum between the 2 and 5 o’clock positions.” (*Id.*) John Kustan, M.D., interpreted petitioner’s MRI. (*Id.*) His assessment was supraspinatus tendinosis, chronic tear of the anterior glenoid labrum, and AC arthrosis with moderate to severe outlet narrowing. (*Id.*)

After the MRI, on December 28, 2016, petitioner returned to PA Eckelman to follow up. (Ex. 3, p. 6.) At the time of the visit, petitioner was experiencing pain “over the lateral aspect of the shoulder, but also tends to have some pain in the elbow, as well as dysesthesias in the fourth and fifth finger.” (*Id.*) PA Eckelman’s diagnosis was osteoarthritis of the AC joint, supraspinatus tendonitis in petitioner’s left shoulder and likely rotator cuff tendonitis. (*Id.* at 6-7.) She also noted that cervical radiculitis was possible. (*Id.* at 6.) Regarding petitioner’s suspected rotator cuff tendonitis, PA Eckelman noted, “I am unsure how this occurred secondary to the flu shot, perhaps due to a localized inflammatory reaction.” (*Id.* at 7.) PA Eckelman recommended physical therapy. (*Id.*)

On February 10, 2017, petitioner again followed up with PA Eckelman. (Ex. 3, p. 4.) PA Eckelman noted petitioner was experiencing ongoing “left shoulder pain after a flu shot with therapy initiated at last visit and continued work restrictions.” (*Id.*) Petitioner reported that she began occupational therapy because her workers’ compensation denied physical therapy. (*Id.*) Petitioner also noted that “despite work restrictions [her] symptoms seem to be worse while at work.” (*Id.*) At the time of the visit, petitioner exhibited discomfort in her left shoulder “with pushing and pulling.” PA Eckelman’s examination revealed tenderness “over the AC joint and the lateral acromion” as well as positive impingement, a positive Hawkins test, and “[m]ild discomfort with rotator cuff testing.” (*Id.*) PA Eckelman again concluded that petitioner “appears to have an inflammatory condition in the shoulder, potentially brought on after an allergic reaction to the flu shot.” (*Id.*) PA Eckelman no longer suspected cervical radiculitis. (*See id.*)

Petitioner attended several occupational therapy sessions throughout January, February, and March 2017. (Ex. 9, pp. 1-12; 16-26; 29-39.) On March 9, 2017, petitioner visited Julie Grosvenor, M.D., at Southern Maine Health Care with complaints of ongoing left shoulder pain despite months of occupational therapy. (Ex. 3, p. 1.) Petitioner described her pain level as a seven out of ten. (*Id.*) Dr. Grosvenor noted that petitioner’s injury occurred five months prior. (*Id.*) Upon examination, petitioner had

tenderness “across the trapezius, at the AC joint, and over the proximal biceps.” (*Id.*) Dr. Grosvenor’s impression was left shoulder pain, supraspinatus tendonitis, and osteoarthritis of the AC joint. (*Id.*) Petitioner received a steroid injection in her left shoulder in the subacromial space. (*Id.* at 2.)

Nearly one month later, on April 5, 2017, petitioner saw occupational therapist Jacqueline Guillemette at Southern Maine Occupational Therapy. (Ex. 3, p. 24.) Ms. Guillemette noted that petitioner showed “improvements in pain, motion,” but that her “strength, edema, and overall functional use of the left shoulder, arm” remained limited. (*Id.*) Ms. Guillemette further noted that “last time [petitioner] discontinued [occupational therapy] too soon, her symptoms of motion, pain, edema, and functional strength worsened rapidly.” (*Id.*) Additionally, Ms. Guillemette observed that petitioner had pain in the left shoulder when at rest, decreased left upper extremity range of motion, and reduced strength. (*Id.* at 25-26.)

Petitioner returned to PA Eckelman on April 21, 2017, to follow up on her left shoulder pain. (Ex. 5, p. 10.) Petitioner noted that the steroid injection she received at her March 9, 2017, visit did not improve her pain. (*Id.*) She stated that occupational therapy had been the most helpful in alleviating her shoulder symptoms. (*Id.*) Petitioner reported feeling numbness and tingling in her left forearm and hand. (*Id.* at 11.) PA Eckelman assessed petitioner with osteoarthritis of the ac joint, rotator cuff tendonitis, and ulnar neuritis. (*Id.*) Petitioner described numbness and tingling “distinctly to the ulnar nerve distribution.” (*Id.*) PA Eckelman ordered an EMG and administered another steroid injection in petitioner’s left shoulder AC joint. (*Id.*)

On April 26, 2017, petitioner visited Christopher Hughes, M.D., at Southern Maine Health Care to address her ongoing left shoulder pain and undergo an EMG study of her left arm and hand. (Ex. 5, p. 13.) Petitioner reported that she was waking up in the morning with numbness and tingling in her left hand. (*Id.*) Petitioner’s EMG study revealed “[c]arpal syndrome of the left hand with chronic axonal injury suggesting long-standing median nerve entrapment.” (*Id.*) Regarding the ulnar nerve, Dr. Hughes observed mild impingement at the wrist given a delay in motor and sensory conduction but no conduction abnormalities across the elbow segment and no axonal injury were identified. (*Id.*) Dr. Hughes did not find any evidence of radiculopathy. (*Id.*) Dr. Hughes sent petitioner home with a left wrist brace. (*Id.*)

PA Eckelman evaluated petitioner for her continued left shoulder pain on May 2, 2017. (Ex. 5, p. 14.) Petitioner told PA Eckelman that the steroid injections had not helped and that despite ongoing therapy and activity restrictions at work, her left shoulder pain persisted. (*Id.*) PA Eckelman noted that “surgical intervention is the next step.” (*Id.*) PA Eckelman further stated, “I am unable to determine why [petitioner] has had a flare of the symptoms after a flu shot, I am uncertain of the relationship.” (*Id.*) Upon examination, petitioner had tenderness at the AC joint and acromion, reduced range of motion, and a positive empty can test. (*Id.* at 15.) PA Eckelman noted that petitioner’s MRI showed “supraspinatus tendonitis without evidence for a tear,” “AC joint arthritis,” and “[c]hronic tear of the anterior glenoid labrum.” (*Id.* at 19.) PA Eckelman

discussed the possibility of a surgical intervention to address petitioner's left shoulder pain and carpal tunnel syndrome. (*Id.* at 20.)

Petitioner underwent a "left carpal tunnel release and left shoulder arthroscopic subacromial decompression and open distal clavicle excision" surgery with Dr. Grosvenor on May 17, 2017. (Ex. 5, p. 25.) Dr. Grosvenor's preoperative diagnosis was "left carpal tunnel syndrome" and "shoulder impingement and AC Joint arthritis." (*Id.*) Petitioner's carpal tunnel release was completed first without complication. (*Id.*) When Dr. Grosvenor began petitioner's left shoulder decompression and clavicle excision, he noted that petitioner's rotator cuff and biceps tendon were normal but that a small area of petitioner's anterior labrum was fraying. (*Id.* at 26.) Dr. Grosvenor used a shaver and cautery device to debride petitioner's bursa and resect soft tissue from the undersurface of the acromion. (*Id.*) He also used a reciprocating saw to resect a distal 5 mm of clavicle to give space to the distal AC joint. (*Id.*)

On May 24, 2017, petitioner saw PA Eckelman for a postoperative examination. (Ex. 5, p. 27.) Petitioner reported full resolution of her dysesthesias. (*Id.*) Petitioner described her pain as a four out of ten but reported doing well after the surgery. (*Id.* at 27-28.) At another follow up visit on July 19, 2017, PA Eckelman noted that petitioner's left shoulder symptoms had improved and that she had good range of motion. (Ex. 9, p. 76.)

Petitioner was seen by family nurse practitioner Hannah Whipple ("Nurse Whipple") on September 25, 2018, for chronic left shoulder pain that recently worsened. (Ex. 11, p. 1.) Petitioner informed Nurse Whipple that her shoulder pain was exacerbated by heaving and frequent lifting. (*Id.*) Nurse Whipple advised petitioner to limit the "aggravating activities." (*Id.*) Petitioner informed Nurse Whipple that she planned to follow up with her orthopedic specialist. (*Id.*) Petitioner did not submit any records documenting her treatment beyond September 25, 2018.

b. As Reflected in Petitioner's Affidavit

Petitioner filed an affidavit on November 29, 2017. (Ex. 8.) Petitioner avers that she received the flu vaccine on October 12, 2016, through her employer. (*Id.* at 1.) Petitioner states that it was the protocol of her employer, Newton Center Nursing and Rehab, for employees to get the flu vaccine or wear masks during flu outbreaks. (*Id.*) Petitioner claims that she chose to get the flu vaccine because she was unable to wear a mask due to her claustrophobia. (*Id.*) She claims that she asked the nurse administering the flu vaccine if the vaccine contained latex, to which the nurse responded that it did not. (*Id.*) Shortly after receiving the vaccine, petitioner avers that her throat started to close, and by the next day, she had a three-inch raised welt on her shoulder. (*Id.*)

On October 13, 2016, petitioner recalls going to a walk-in clinic for her suspected allergic reaction to the flu vaccine. (Ex. 8, p. 1.) Petitioner confirms that she was transferred to the ER via ambulance and treated for anaphylaxis at Sothorn Main Health

Care. (*Id.*) Petitioner states that she was given an IV, Benadryl, and a prednisone prescription. (*Id.*)

In her affidavit, petitioner claims that her shoulder pain returned after she finished her course of prednisone. (*Id.*) Petitioner avers that she was referred to Dr. Courtney, an infectious disease specialist, to discuss whether she should receive future vaccines. (*Id.*) When she saw Dr. Courtney on October 31, 2016, petitioner recalls Dr. Courtney advising her to avoid future flu vaccines. (*Id.*) Petitioner remembers Dr. Courtney telling her that her pain would resolve in time; however, petitioner avers that her shoulder pain progressively worsened and that she began to experience numbness and throbbing. (*Id.*)

Petitioner recalls seeing Nurse Hill for her shoulder pain on December 9, 2016. (Ex. 8, p. 2.) Petitioner states that Nurse Hill recommended she take ibuprofen for the pain and follow up with an orthopedic specialist. (*Id.*) Petitioner avers that she saw an orthopedic specialist, who recommended physical or occupational therapy as well as a cortisone shot. (*Id.*) She states that occupational therapy did not help. (*Id.*) In a signed statement dated November 28, 2018, petitioner clarifies that she underwent occupational therapy from January 2017 to April 2017 at Southern Maine Health Care Rehab Services. (Ex. 12.) Petitioner confirms that she never pursued physical therapy. (*Id.*)

On May 12, 2017, petitioner underwent surgery for her shoulder symptoms. (Ex. 8, p. 2.) Petitioner attests that she was unable to work for approximately two weeks after her surgery. (*Id.*) When petitioner returned to work, she states that she was limited to answering phones and completing paperwork for nearly two months. (*Id.*) She states that on July 19, 2017, her orthopedist cleared her to perform “less restrictive work” for two weeks, after which she could resume normal work responsibilities. (*Id.*)

Petitioner avers that she had no history of shoulder pain prior to vaccination. (Ex. 8, p. 2.) She claims that she continues to experience pain in her shoulder while performing daily activities such as doing the dishes, mowing the lawn, and getting ready for the day. (*Id.*)

IV. Expert Opinions

a. Petitioner’s Experts

i. Clifford J. Colwell, Jr., M.D.

Petitioner offered several reports from Dr. Colwell in support of her claim. Dr. Colwell is a board-certified orthopaedic surgeon and currently serves as medical director of the Shiley Center for Orthopaedic Research and Education at the Scripps Clinic in La Jolla, California. (Ex. 13, p. 1; Ex. 14, p. 3.) He received his medical degree from the University of Michigan, completed his orthopedic residency at the Hospital for Special Surgery in New York City, and was a trauma fellow at Los Angeles

County Hospital. (Ex. 13, p. 1; Ex. 14, p. 1.) From 1968 to 1970, he was an orthopaedic surgeon in the military at Carswell Air Force Base in Fort Worth, Texas. (Ex. 13, p. 1; Ex. 14, p. 1.) For twenty years, he was the chief of the Orthopaedic Division at Scripps Clinic and Director of the Lower Extremity Reconstruction Fellowship Program. (Ex. 13, p. 1; Ex. 14, p. 2.) He was also the team physician for the San Diego Padres for twenty-five years. (Ex. 13, p. 1; Ex. 14, p. 3.) Additionally, he previously served as a clinical professor in the Department of Orthopaedics and Rehabilitation at the University of California, San Diego School of Medicine and an adjunct clinical professor at the Department of Basic Science and Clinical Research at The Scripps Research Institute. (Ex. 13, p. 1; Ex. 14, p. 2.)

Regarding the onset of petitioner's shoulder pain, Dr. Colwell noted that petitioner sought medical care the day after receiving the flu vaccine and was assessed with an allergic reaction to the vaccine. (Ex. 13, p. 2 (citing Ex. 3, p. 11.)) Dr. Colwell emphasized that the notes from this medical visit indicated that petitioner "had pain and severe itching at the site of injection immediately following" the vaccination. (*Id.* (quoting Ex. 3, p. 11.)) Dr. Colwell heavily relied on notes from petitioner's medical providers associating the onset of petitioner's left shoulder pain with receipt of the flu vaccine. (See *id.* (citing Ex. 6, pp. 8-9 (Dr. Upham); Ex. 2, pp. 29, 33 (Nurse Hill); Ex. 2, p. 81 (Dr. Courtney); Ex. 3, p. 8 (PA Eckelman); Ex. 3, p. 1 (Dr. Grosvenor); Ex. 5, p. 10 (occupational therapy)).) Although Dr. Colwell acknowledged that petitioner's immediate pain briefly subsided and later returned, he explained that this is "not uncommon with the onset of shoulder injuries." (*Id.*) With respect to the role of petitioner's prednisone use shortly after receiving the flu vaccine, Dr. Colwell opined that prednisone is a powerful anti-inflammatory that may have temporarily masked petitioner's pain. (Ex. 18, p. 1.) He stated that petitioner's prednisone use explains why her pain and inflammation decreased but returned after stopping the drug. (*Id.*) Therefore, Dr. Colwell maintained that petitioner experienced shoulder pain within forty-eight hours of vaccination.

Dr. Colwell disagreed with Dr. Feeley's assertion that while petitioner experienced an immediate allergic reaction to the flu vaccine, she did not develop shoulder pain until later. (Ex. 16, p. 1.) He reiterated that "many of [petitioner's] early records discuss her pain." (*Id.*) Although Dr. Colwell maintained that petitioner's shoulder pain began within forty-eight hours of vaccination, he appeared to suggest that petitioner could establish causation even if her pain did not manifest until later. (See *id.*) To support a longer temporal association between vaccination and injury, Dr. Colwell discussed the medical literature Dr. Feeley offered. He acknowledged the Martín-Arias article shows that most SIRVA patients experience pain within twenty-four hours; however, he asserted that "the article appears to support a latency period that is as long as 4-7 days." (*Id.* (citing L.H. Martín Arias et al., *Risk of Bursitis and Other Injuries and Dysfunctions of the Shoulder Following Vaccination*, 35 VACCINE 4870 (2017) (Ex. 22; Ex. A, Tab 5a)).) Dr. Colwell further asserted that the Atanasoff et al. article demonstrates that 8% of the study's subjects did not experience vaccine-related shoulder pain until four days post-vaccination. (*Id.* (citing S. Atanasoff et al., *Shoulder Injury Related to Vaccine Administration (SIRVA)*, 28 VACCINE 8049 (2010) (Ex. 17; Ex.

21; Ex. A, Tab 3)).) Based on these studies, Dr. Colwell concluded that “the appropriate temporal relationship between vaccination and injury may well be longer than 48 hours and may well be as long as 7 days.” (*Id.*)

Dr. Colwell opined that petitioner’s left shoulder pain and limited range of motion was caused by the flu vaccine. (Ex. 13, p. 3.) Dr. Colwell discussed petitioner’s EMG performed on April 26, 2017, which showed no evidence of radiculopathy. (*Id.* (citing Ex. 5, p. 13).) Although the EMG showed evidence of carpal tunnel syndrome, Dr. Colwell explained that this would account for some of the symptoms in petitioner’s left hand but would not contribute to petitioner’s “significant shoulder issues.” (*Id.*) In response to Dr. Feeley’s assertion that the lack of fluid in petitioner’s subacromial bursa evidenced by her MRI indicates that petitioner’s bursitis was not acute, Dr. Colwell explained that MRI reports must be interpreted with the patient’s physical symptoms in mind. (Ex. 18, p. 1.) Dr. Colwell opined that the absence of fluid does not suggest that there was no inflammation in petitioner’s shoulder. (*Id.*) Thus, Dr. Colwell concluded that no condition or abnormality other than the vaccine would adequately explain petitioner’s left shoulder symptoms.

ii. Uma Srikuraman, M.D.

Petitioner also offered an expert opinion from Dr. Srikumaran. Dr. Srikumaran received his medical degree from Johns Hopkins School of Medicine and completed a fellowship in shoulder surgery at Harvard School of Medicine. (Ex. 19, p. 1; Ex. 20, p. 1.) Dr. Srikumaran is currently an associate professor in the shoulder division at the Johns Hopkins School of Medicine and serves as the Shoulder Fellowship Director and Chair of Orthopaedic Surgery at the Howard County General Hospital. (Ex. 19, p. 1; Ex. 20, p. 1.) Additionally, he works as the Medical Director for the Johns Hopkins Musculoskeletal Service Line in Columbia, Maryland. (Ex. 19, p. 1; Ex. 20, p. 2.) Each year, Dr. Srikumaran sees about 2500-3000 patients with shoulder issues and performs 400-500 shoulder surgeries per year. (Ex. 19, p. 1.)

Dr. Srikumaran opined that petitioner experienced shoulder pain within forty-eight hours of vaccination. (Ex. 19, pp. 10-11.) To support this assertion, Dr. Srikumaran noted that petitioner reported pain in her arm at the injection site the day after vaccination. (*Id.* at 10.) In response to Dr. Feeley’s assertion that petitioner did not experience onset until one-week after vaccination, Dr. Srikumaran opined that petitioner’s presentation and the documentation of her pain following vaccination is explained by the Benadryl she received on October 13, 2016, and her five-day course of prednisone. (*Id.* at 10-11 (citing Ex. 6, p. 2).) He agreed with Dr. Colwell that prednisone can temporarily relieve inflammatory pain. (Ex. 19, p. 10.) Dr. Srikumaran explained that petitioner’s shoulder pain temporarily abated because the prednisone “blunt[ed] inflammation everywhere in [petitioner’s] body, including her shoulder and subacromial bursa.” (*Id.*; see also Ex. 30, p. 1 (stating that “the early administration of potent anti-inflammatories clouds the typical presentation of an acute bursitis”).)

Although Dr. Srikumaran maintained that petitioner experienced onset within forty-eight hours of vaccination, he asserted that seven days is an appropriate timeframe for onset following vaccination. (Ex. 19, pp. 13-14.) Dr. Srikumaran cited the Martín Arias et al. article, which demonstrates that shoulder injuries can extend beyond forty-eight hours after vaccination. (Ex. 30, p. 5 (citing Martín Arias et al., *supra*, at Ex. 22 and Ex. A, Tab 5a).) Therefore, even if petitioner experienced onset one week after vaccination as Dr. Feeley suggested, Dr. Srikumaran opined that it would still be a reasonable time interval to infer vaccine-causation.

In response to Dr. Feeley's contention that AC joint arthritis was a potential source of petitioner's pain, Dr. Srikumaran stressed that PA Eckelman noted a negative AC joint crossover test of December 16, 2016. (Ex. 19, p. 11.) Dr. Srikumaran emphasized that if petitioner's AC joint was the primary source of her pain, the crossover test would have been positive. (*Id.*) Dr. Srikumaran further noted that PA Eckelman documented positive Neer's and Hawkins tests, which are consistent with rotator cuff tendonitis or bursitis. (*Id.*) Additionally, Dr. Srikumaran opined that had petitioner's AC joint been the only cause of her pain, an isolated distal clavicle excision would have been sufficient to address her shoulder problems; however, petitioner underwent a subacromial decompression and an open distal clavicle excision. (*Id.* at 12.) Dr. Srikumaran explained that the use of a shaver and cautery device to debride petitioner's bursa and resect the soft tissue from the undersurface of the acromion would have been unnecessary if petitioner's bursa was normal. (*Id.*) Although Dr. Srikumaran acknowledged that AC joint arthritis can cause bursitis, he emphasized that petitioner was asymptomatic prior to vaccination. (Ex. 30, pp. 1-2.)

Regarding Dr. Feeley's statement that petitioner's symptoms may have been related to cervical radiculopathy, Dr. Srikumaran asserted that petitioner's tingling in her hand was unrelated to her shoulder injury. (Ex. 19, p. 11.) He explained that radiculopathy would not explain petitioner's shoulder symptoms indicative of bursitis such as pain with motion and positive Neer's and Hawkins tests. (*Id.*; Ex. 30, p. 2.) Dr. Srikumaran further noted that radiculopathy was ruled out by petitioner's EMG. (Ex. 19, p. 11 (citing Ex. 5, p. 13).) In contrast, Dr. Srikumaran agreed with Dr. Colwell that petitioner's EMG indicated carpal tunnel syndrome, which would explain her hand tingling. (*Id.*) Therefore, Dr. Srikumaran concluded that petitioner's left shoulder pain was attributable to an acute vaccine-caused bursitis. (*Id.* at 11-12; Ex. 30, pp. 1-2.)

Dr. Srikumaran also offered a medical theory by which the flu vaccine can cause bursitis and shoulder inflammation. Dr. Srikumaran opined that the antigens in certain vaccines, which are usually injected high into the deltoid muscle, can trigger an inflammatory response in and around the bursa. (Ex. 19, pp. 13-14.) According to Dr. Srikumaran, this can result in inflammation of the tendons and bursa. (*Id.*) In petitioner's case, Dr. Srikumaran opined that the "injection of [a] vaccine antigen into [petitioner's] subacromial bursa led to a 'robust local immune and inflammatory response'" that caused a "pathology of the subacromial space, biceps tendon, glenohumeral joint and capsulitis." (*Id.* at 13 (citing Marko Bodor & Enoch Montalvo, *Vaccine-Related Shoulder Dysfunction*, 25 VACCINE 585 (2007) (Ex. 23)).)

To support his medical theory, Dr. Srikumaran offered several medical articles. He explained that the Atanasoff et al. article “conclude[ed] that vaccine antigen injected into synovial tissue has the potential for inducing a prolonged immune-mediated inflammatory reaction.” (*Id.* (citing Atanasoff et al., *supra*, at Ex. 17, Ex. 21, and Ex. A, Tab 3); see also Ex. 30, p. 5 (discussing the Atanasoff et al. study and asserting that “the rapid onset of pain with limited motion suggests an immune reaction to a previously sensitized shoulder, rather than typical mechanical etiologies of shoulder pain”).) Additionally, he stated that the Martín Arias et al. article “surmise[s] the cause to be an immune mediated response of inflammation related to antigens injected into the bursal tissue.” (Ex. 19, p. 13 (citing Martín Arias et al., *supra*, at Ex. 22 and Ex. A, Tab 5a).) He further claimed that the Dumonde animal study and Trollmo human study “support the clinical literature suggesting the plausibility of inflammation caused by an immune mediated response to antigenic material.” (Ex. 19, p. 3 (citing D.C. Dumonde & L.E. Glynn, *The Production of Arthritis in Rabbits by an Immunological Reaction to Fibrin*, 43 BRITISH J. EXPERIMENTAL PATHOLOGY 373 (1962) (Ex. 24); C. Trollmo, H. Carlsten, & A. Tarkowski, *Intra-Articular Immunization Induces Strong Systemic Immune Response in Humans*, 82 CLINICAL EXPERIMENTAL IMMUNOLOGY 384 (1990) (Ex. 28)).)

Dr. Srikumaran also cited an epidemiological study showing an association between vaccination and shoulder bursitis to support his medical theory. (Ex. 19, p. 13 (citing Elizabeth M. Hesse et al., *Risk for Subdeltoid Bursitis After Influenza Vaccination: A Population-Based Cohort Study*, 173 ANNALS INTERNAL MED. 253 (2020) (Ex. 26)).) The Hesse et al. study concluded that the association between vaccination and shoulder bursitis was more than a “coincidence” and found an increased risk of subdeltoid bursitis following the flu vaccine. (Ex. 19, p. 13 (citing Hesse et al., *supra*, at Ex. 26).) Thus, based on the scientific literature, Dr. Srikumaran concluded that it is biologically plausible that the flu vaccine can cause bursitis. (Ex. 19, pp. 13-14; Ex. 30, pp. 3-7.)

b. Respondent’s Expert, Brian Feeley, M.D.

Respondent offered an expert opinion from Dr. Feeley to defend the claim. Dr. Feeley is a board-certified orthopaedic surgeon. (Ex. A, p. 1; Ex. B, p. 1.) He received his medical degree from Stanford University in 2001, completed a research-focused orthopaedic surgery residency at the University of California, Los Angeles in 2007, and completed a sports medicine and shoulder fellowship at the Hospital for Special Surgery in New York in 2008. (Ex. A, p. 1; Ex. B, p. 1.) Dr. Feeley has practiced as an orthopaedic surgeon at the University of California, San Francisco since 2008, where he sees patients with shoulder and knee injuries. (Ex. A, p. 1; Ex. B, p. 1.) He also currently serves as a professor in residence. (Ex. A, p. 1; Ex. B, p. 1.) Dr. Feeley is a member of the American Academy of Orthopaedic Surgeons, American Orthopedic Sports, American Shoulder and Elbow Society, and American Orthopaedic Association. (Ex. A, p. 1; Ex. B, p. 5.) He has published over 150 peer-reviewed manuscripts, several review papers and book chapters, and a book on rotator cuff tears. (Ex. A, p. 1; Ex. B, pp. 23-36.)

Dr. Feeley opined that petitioner's shoulder injury did not occur within forty-eight hours of vaccination. (Ex. A, pp. 6-7; see Ex. 10, p. 10.) Dr. Feeley noted that while petitioner reported immediate pain and itching at the injection site, these symptoms were related to her allergic reaction and not to her bursitis. (Ex. A, p. 6.) Dr. Feeley explained that onset of bursitis is characterized by an "acute and persistent onset of pain that does not wax and wane over the first few weeks." (*Id.* at 6-7.) Therefore, he asserted that it would be atypical presentation for petitioner's pain to temporarily subside. (*Id.*) With respect to petitioner's experts' assertion that petitioner's prednisone course masked her pain, Dr. Feeley agreed that prednisone is a powerful anti-inflammatory and that it was properly prescribed to petitioner to treat her allergic reaction to latex. (Ex. C, p. 1.) However, Dr. Feeley emphasized that petitioner reported increasing shoulder pain while on prednisone. (Ex. D, p. 2 (citing Ex. 6, p. 5 (reporting shoulder aches after a few days on prednisone); Ex. 3, p. 8 (reporting increasing shoulder pain that gradually worsened approximately one day after starting prednisone))).) Therefore, Dr. Feeley maintained that the onset of petitioner's shoulder pain attributable to her bursitis did not occur until one-week post-vaccination. (Ex. A, p. 7.)

While Dr. Feeley agreed that petitioner was appropriately diagnosed with bursitis, he challenged petitioner's experts' conclusion that petitioner had acute bursitis caused by inflammation from the flu vaccine. (Ex. A, pp. 5, 8.) He claimed that the pain petitioner reported immediately following vaccination was inconsistent with localized shoulder symptoms associated with acute bursitis, such as pain with range of motion and lifting and nighttime pain. (*Id.* at 5, 7.) In contrast, Dr. Feeley maintained that petitioner's reports of "acute generalized musculoskeletal aching and general malaise" were more consistent with normal side effects of the flu vaccine rather than an acute bursitis. (*Id.* at 7.) Additionally, he emphasized that petitioner's MRI eight weeks after vaccination did not show bursal fluid. (*Id.* at 7-8; Ex. D, p. 2 (citing Ex. 3, p. 18).) He stressed that if petitioner had an acute bursitis caused by inflammation from the flu vaccine, petitioner would have had persistent fluid accumulation in the shoulder. (Ex. A, p. 8; Ex. D, p. 2.) Thus, Dr. Feeley concluded that petitioner's presentation and MRI findings were inconsistent with an acute bursitis caused by a vaccine-related inflammatory event.

Dr. Feeley opined that petitioner's symptoms were more likely caused by AC joint arthritis. (Ex. A, p. 5; Ex. D, pp. 1-2.) Dr. Feeley noted that petitioner's MRI showed "evidence of severe outlet narrowing from a chronic AC joint arthritis." (Ex. A, p. 7; Ex. C, p. 1.) He also noted that petitioner's grinding sensation could have been a symptom of AC joint arthritis and that petitioner had tenderness at the AC joint. (Ex. C., p. 1 (citing Ex. 2, pp. 33, 35).) Dr. Feeley agreed with Dr. Srikumaran that petitioner had no shoulder pain prior to vaccination and that the medical records related to petitioner's AC joint were "inconsistent." (Ex. D, p. 2.) He conceded that although petitioner's MRI supported a diagnosis of AC joint arthritis, this is common in people over forty years of age and does not necessarily suggest a symptomatic pathology. (*Id.*) He also acknowledged that petitioner's AC joint injection did not relieve her pain. (*Id.*) Although he recognized that AC joint arthritis could not account for all of petitioner's symptoms,

he maintained that chronic AC joint arthritis was the more likely cause of petitioner's bursitis. (*Id.* at 1-2.)

Dr. Feeley also offered cervical radiculopathy as an alternative source of petitioner's symptoms. (Ex. A, pp. 5, 8; Ex. D, pp. 2-3.) He noted that petitioner described symptoms such as weakness, numbness, and tingling radiating to her hand. (Ex. A, pp. 5, 8.) Dr. Feeley asserted that "[t]hese symptoms were separate and distinct from her diagnosis of carpal tunnel syndrome." (*Id.* at 5.) He explained that carpal tunnel syndrome affects the thumb, index, and middle fingers, but not the fourth and fifth fingers. (Ex. D, pp. 2-3.) Dr. Feeley conceded that petitioner's EMG showed no evidence of cervical radiculopathy. (Ex. A, p. 8.) However, he opined that petitioner's EMG was several months after she complained of these radicular symptoms, and suggested that petitioner's cervical radiculopathy could have resolved with physical therapy.⁴ (*Id.*) He elaborated patients with normal EMG findings can still have cervical radiculopathy, "especially in relatively mild cases." (Ex. D, p. 3.) Dr. Feeley also claimed that petitioner's cervical spine was never "fully evaluated." (*Id.* at 2.) Based on Dr. Feeley's belief that petitioner's symptoms were more likely caused by AC joint arthritis or cervical radiculopathy, he concluded that petitioner did not suffer vaccine-related acute bursitis.

V. Discussion

a. Table SIRVA Analysis

In this case, petitioner's Table Injury claim hinges on the second SIRVA QAI prong, which requires the petitioner's pain to occur within the specified timeframe of forty-eight hours. Petitioner alleges that the medical records show that petitioner experienced shoulder pain within forty-eight hours of vaccination. (ECF No. 53, p. 10 (citing Ex. 3, p. 11).) Conversely, respondent contends that petitioner's pain related to her bursitis did not occur within the specified timeframe. (ECF No. 56, pp. 18-19.)

Petitioner primarily relies on the medical records from her visit to the walk-in clinic the day following vaccination to support a finding that the onset of her shoulder pain began within forty-eight hours of vaccination. (ECF No. 53, p. 10 (citing Ex. 3, p. 11).) On October 13, 2016, the day after receiving the flu vaccine, petitioner presented to Nurse Waitt at a walk-in clinic for an allergic reaction to the latex contained in the flu shot. (Ex. 3, p. 11.) Petitioner reported "pain and severe itching at the site of injection immediately following" receipt of the flu vaccine. (*Id.*) She also stated that her throat felt like it was closing. (*Id.*) Nurse Waitt administered an intramuscular dose of Benadryl and recommended petitioner go to the ER. (*Id.* at 11-12.) Upon presentation to the ER at Southern Maine Health Care, petitioner told PA Chaffey that she experienced itching at the injection site within minutes of vaccination and later felt like her throat was closing. (Ex. 6, pp. 2-3.) Petitioner was diagnosed with an allergic reaction and prescribed a five-day course of prednisone. (*Id.*)

⁴ Petitioner never attended physical therapy, though she participated in occupational therapy. (Ex. 12.)

Given that prednisone is a powerful anti-inflammatory, petitioner's experts are persuasive in opining that the actual onset of petitioner's acute bursitis may have been masked by her five-day course of prednisone. However, although petitioner's onset was likely close in time to vaccination, I am not convinced that petitioner's medical records generated within forty-eight hours of vaccination demonstrate musculoskeletal shoulder pain rather than local injection site pain related to her allergic reaction. Petitioner's medical records from her visit to the walk-in clinic on October 13, 2016, document that petitioner experienced local pain and itching at the injection site and that her throat felt like it was closing, which is consistent with an allergic reaction. (Ex. 3, p. 11; see also Ex. A, pp. 6-7 (Dr. Feeley opining that petitioner's immediate symptoms were consistent with an allergic reaction).)

Further, petitioner's affidavit does not specifically assert shoulder joint pain from the outset and suggests that her shoulder pain truly began after her course of prednisone. (See Ex. 8, p. 1.) This is confirmed by the subsequent medical records. On October 20, 2016, Dr. Upham noted that petitioner completed her prednisone course "without any problem" but that she experienced shoulder aching "after a few days on the prednisone." (Ex. 6, p. 5.) Based on the entire record, although petitioner's onset occurred close in time to vaccination, there is not preponderant evidence to support a finding that her musculoskeletal shoulder pain began specifically within forty-eight hours of vaccination.

Given that petitioner is unable to establish that her bursitis-related shoulder pain began within forty-eight hours of vaccination, petitioner's claim for a Table Injury of SIRVA must fail. Therefore, it is unnecessary to discuss the remaining SIRVA QAI prongs.

b. Cause-in-Fact Analysis

As explained above, petitioner has not established that she suffered a Table Injury of SIRVA. Accordingly, petitioner's burden is to demonstrate by preponderant evidence each of the three *Althen* prongs used to determine actual causation (i.e., an acceptable medical theory, a logical sequence of cause and effect, and a proximate temporal relationship). *Althen*, 418 F.3d at 1278.

i. Althen Prong One

Under *Althen* prong one, petitioner must provide a "reputable medical theory," demonstrating that the vaccine received can cause the type of injury alleged. *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355-56 (Fed. Cir. 2006) (citations omitted). Such a theory must only be "legally probable, not medically or scientifically certain." *Knudsen*, 35 F.3d at 549. Petitioner may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1378-79 (Fed. Cir. 2009) (citing *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1325-26 (Fed. Cir. 2006)). However, "[a]

petitioner must provide a ‘reputable medical or scientific explanation’ for [her] theory. While it does not require medical or scientific certainty, it must still be ‘sound and reliable.’” *Boatmon*, 941 F.3d at 1359 (quoting *Knudsen*, 35 F.3d at 548-49).

Respondent is correct that to establish a cause-in-fact claim, petitioner bears the burden of providing a medical theory that goes beyond merely repeating the Table SIRVA criteria. See *Kelly v. Sec’y of Health & Human Servs.*, No. 17-1918V, 2022 WL 1144997, at *21 (Fed. Cl. Spec. Mstr. Mar. 24, 2022) (ruling that a “petitioner may not merely rely on the fact that SIRVA was added to the Vaccine Injury Table to establish a medical theory for a cause-in-fact claim”). As discussed above, petitioner has not met the criteria required to establish a Table Injury of SIRVA. However, through Dr. Srikumaran, petitioner has offered a reputable medical theory that goes beyond merely reiterating the SIRVA criteria.

Dr. Srikumaran opined that vaccine antigens injected into synovial tissue can cause a “prolonged immune-mediated inflammatory reaction.” (Ex. 19, p. 13 (citing Atanasoff et al., *supra*, at Ex. 17, Ex. 21, and Ex. A, Tab 3.)) To support this contention, Dr. Srikumaran offered several medical articles examining post-vaccination shoulder pain. (Ex. 19, pp. 13-14; Ex. 30, pp. 3-6.) The Atanasoff study found an association between vaccination and shoulder injury based on the subjects’ lack of prior shoulder symptoms and rapid onset of pain following vaccination. (Atanasoff et al., *supra*, at Ex. 17, Ex. 21, and Ex. A, Tab 3, p. 8051.) The Atanasoff authors surmised that an immune-mediated inflammatory reaction induced by the vaccine caused the subjects’ shoulder symptoms. (*Id.*) Given that there is no diagnostic test available to determine whether shoulder dysfunction is vaccine-caused, the Atanasoff authors emphasized the importance of evaluating clinical presentation in identifying post-vaccination shoulder injuries. (*Id.* at 8052.) Dr. Srikumaran’s theory is further supported by the Bodor and Montalvo case reports that found that injection into the subdeltoid bursa likely caused “a robust local immune and inflammatory response.” (Bodor & Montalvo, *supra*, at Ex. 23, p. 586.) Bodor and Montalvo concluded that “[g]iven that the subdeltoid bursa is contiguous with the subacromial bursa, [the injection] led to a subacromial bursitis, bicipital tendonitis, and inflammation of the shoulder capsule.” (*Id.*)

Significantly, Dr. Srikumaran also presented the Hesse et al. study, which confirms an epidemiological risk of post-vaccination bursitis. The study examined nearly three million people who received the 2016-2017 seasonal flu vaccine and looked for incidences of subdeltoid bursitis diagnosed within 180 days of vaccination. (Hesse et al., *supra*, at Ex. 26, p. 253.) The Hesse et al. authors “identified a small risk for subdeltoid bursitis with new symptom onset after injection of an influenza vaccine.” (*Id.* at 259.) The Hesse et al. study specifically demonstrated bursitis as a statistically significant epidemiological finding rather than simply a clinical observation. (See *id.*) Taken together, the literature offered by Dr. Srikumaran supports the theory that the flu vaccine can cause bursitis. Accordingly, petitioner has offered a reputable causal theory sufficient to meet her burden under *Althen* prong one.

ii. Althen Prong Two

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375-77; *Capizzano*, 440 F.3d at 1326; *Grant*, 956 F.2d at 1148. In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 (quoting *Althen*, 418 F.3d at 1280) (stating that "medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'"). However, medical records and/or statements of a treating physician's views do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. See Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Human Servs.*, 88 Fed. Cl. 706, 746 n.67 (2009) (stating that "there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted").

To support a logical sequence of cause and effect, Dr. Srikumaran relies on the presence of acute bursitis. (See Ex. 19, pp. 11-12; Ex. 30, pp. 1-2.) The experts agree that petitioner suffered bursitis and was asymptomatic prior to vaccination. (See Ex. A, p. 5; Ex. D, pp. 1-2.) However, contrary to Dr. Colwell and Dr. Srikumaran, Dr. Feeley argues that petitioner's presentation was inconsistent with an acute bursitis. (Ex. A, pp. 5-8.) Dr. Feeley takes issue with the fact that petitioner's MRI did not show fluid collection, which he claims suggests that petitioner's bursitis was not acute. (*Id.* at 7-8; Ex. D, p. 2.) Dr. Feeley does not provide any medical literature to support his assertion that the absence of fluid in the subacromial bursa suggests a chronic rather than acute process. (See Ex. A, pp. 7-8; Ex. D, p. 2.) Dr. Colwell asserts that the absence of fluid in the subacromial bursa on petitioner's MRI does not rule out acute bursitis. (See Ex. 18, p. 1.) Additionally, Dr. Srikumaran emphasizes that regardless of the MRI findings, petitioner's surgery required use of a shaver and cautery device to debride the bursa and resect the soft tissue from the undersurface of the acromion. (Ex. 19, p. 12 (citing Ex. 5, p. 26).) To Dr. Srikumaran, this is strongly suggestive of an acute process because the use of a shaver and cautery device would be unnecessary if petitioner's bursa was normal. (*Id.*) Additionally, petitioner had positive Neer's and Hawkins tests, which Dr. Srikumaran explains is consistent with acute bursitis. (*Id.* at 11.) Therefore, regardless of petitioner's MRI findings, both Dr. Colwell and Dr. Srikumaran opine that petitioner's presentation suggests an acute bursitis.

Further, Dr. Feeley's alternative explanations for petitioner's shoulder pain are not persuasive. Dr. Srikumaran persuasively opined that petitioner's presentation is not adequately explained by AC joint arthritis. (Ex. 19, pp. 11-12; Ex. 30, pp. 1-2.) PA Eckelman noted a negative AC joint crossover test on December 16, 2016, which indicates that problems with petitioner's AC joint would not adequately explain her

symptoms. (Ex. 3, p. 9; *see also* Ex. 19, p. 11.) Additionally, the fact that petitioner was asymptomatic prior to vaccination indicates that chronic AC joint arthritis was not the primary source of her pain. (Ex. 30, pp. 1-2.) Dr. Feeley conceded that petitioner's AC joint arthritis is inconsistently demonstrated in the medical records and agreed that it would not explain all of petitioner's symptoms. (Ex. D, p. 2.) Although petitioner's MRI showed evidence of AC joint arthritis, Dr. Feeley stated that this is common in individuals over forty years of age and indicated that many patients with AC joint arthritis are asymptomatic. (*Id.*) Dr. Feeley also acknowledged that petitioner's AC joint injection did not relieve her pain. (*Id.*) He concluded that AC joint arthritis could "not account for all of [petitioner's] pain." (*Id.*)

Moreover, cervical radiculopathy does not explain petitioner's shoulder dysfunction. Dr. Feeley acknowledged that petitioner's EMG showed no evidence of cervical radiculopathy. (Ex. A, p. 8.) He did not extensively address why petitioner's EMG would not show evidence of cervical radiculopathy beyond stating that petitioner's EMG was taken months after she first complained of radicular symptoms and that it could have resolved with physical therapy—which petitioner never attended. (*Id.*; *see also* Ex. 12.) This assertion lacks persuasiveness because as evidenced by the medical records, petitioner's radicular symptoms, including hand tingling, were ongoing at the time of her EMG and did not resolve with occupational therapy. (Ex. 5, p. 10 (reporting ongoing numbness and tingling in her left forearm and hand even after attending occupational therapy); *id.* at 13 (reporting hand tingling at the time of her EMG).) Rather, petitioner's experts both convincingly attributed petitioner's hand tingling to her carpal tunnel syndrome, which was unrelated to her shoulder dysfunction. (Ex. 13, p. 3 (Dr. Colwell); Ex. 19, p. 11 (Dr. Srikumaran).) Even still, none of petitioner's treating physicians ultimately felt she had cervical radiculopathy.⁵

Based on the medical records, petitioner's clinical course is more consistent with a post-vaccination acute process. First, as discussed above, petitioner had no left shoulder pain prior to vaccination. Additionally, as stressed by Dr. Srikumaran, petitioner's bursal dysfunction was confirmed by surgery. (Ex. 19, p. 12.) Further, petitioner derives some support from her treaters. (*See, e.g.*, Ex. 2, p. 81 (Dr. Courtney assessing petitioner has having an "[a]dverse reaction either hypersensitivity reaction or rigorous immune response from prior vaccination" and recommending petitioner "avoid revaccination from injectable influenza vaccine from here on"); Ex. 3, pp. 1, 9 (Dr. Grosvenor and PA Eckelman noting that petitioner "appears to have an inflammatory condition in the shoulder, potentially brought on after an allergic reaction to the flu shot"). Finally, neither AC joint arthritis nor cervical radiculopathy entirely explains petitioner's presentation. Therefore, petitioner's treatment course suggests a vaccine-mediated acute bursitis. Accordingly, petitioner has satisfied *Althen* prong two.

⁵ PA Eckelman initially suspected cervical radiculitis, noting it in her reports on December 16th and 28th, 2016. (Ex. 3, pp. 6, 8.) However, there is no mention of cervical etiology in any of PA Eckelman's subsequent reports. (*See* Ex. 3, 5.) Radiculitis was also noted in petitioner's Workers' Compensation file. (Ex. 10, p. 7.) Petitioner's Workers' Compensation claim was denied with the reason being "pre-existing condition" and the comments reflecting that "[t]reatment for left shoulder is not related to reported 10/12/16 incident." (*Id.* at 22.)

iii. Althen Prong Three

The third *Althen* prong requires establishing a “proximate temporal relationship” between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase “medically-acceptable temporal relationship.” *Id.* A petitioner must offer “preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder’s etiology, it is medically acceptable to infer causation.” *de Bazan v. Sec’y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must coincide with the theory of how the relevant vaccine can cause an injury (*Althen* prong one’s requirement). *Id.*; *Shapiro v. Sec’y of Health & Human Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. den’d after remand*, 105 Fed. Cl. 353 (2012), *aff’d mem.*, 503 Fed. App’x 952 (Fed. Cir. 2013); *Koehn v. Sec’y of Health & Human Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review den’d*, (Fed. Cl. Dec. 3, 2013), *aff’d*, 773 F.3d 1239 (Fed. Cir. 2014).

Dr. Feeley contends that most cases of vaccine-related acute bursitis occur within twenty-four hours of vaccination, with forty-eight hours as the outer limit. (Ex. A, p. 6.) However, the scientific literature filed in this case suggests that while onset of vaccine-related acute bursitis usually occurs within forty-hours of vaccination, it does not always. The Atanasoff et al. article found that one of thirteen patients (8%) experienced onset of shoulder pain within four days of vaccination. (Atanasoff et al., *supra*, at Ex. 17, Ex. 21, and Ex. A, Tab 3.) Additionally, the Martín Arias et al. article supports an onset of shoulder injuries following vaccination that extends to seven days. (Martín Arias et al., *supra*, at Ex. 22, Ex. A, Tab 5a.) The Hesse et al. epidemiological study found that while “most shoulder vaccine adverse event cases in the literature reported symptom onset within this 48-hour interval, there are previous reports of events considered to be vaccine-associated with more prolonged symptom onset intervals.” (Hesse et al., *supra*, at Ex. 26, p. 259.) On petitioner’s behalf, both Dr. Colwell and Dr. Srikumaran opine that an appropriate timeframe between vaccination and onset can extend to one week. (Ex. 16, p. 1; Ex. 19, pp. 13-14.)

Here, although petitioner’s experts opine that up to seven days post-vaccination is medically reasonable, I do not reach the specific question of whether the reasonable outer limit extends as far as seven days post-vaccination. As explained with respect to petitioner’s Table claim, petitioner’s experts are persuasive in opining that onset of petitioner’s shoulder pain was masked by her Prednisone treatment and likely occurred earlier than reported even though petitioner cannot prove that onset was specifically within 48 hours of vaccination. Moreover, Dr. Feeley acknowledges that petitioner reported onset aching shoulder pain even before completing her course of Prednisone. (Ex. D, p. 2 (citing Ex. 6, p. 5).) Specifically, petitioner reported aching pain beginning “after a few days on the Prednisone.” (Ex. 6, p. 5.) Thus, although a precise onset is impossible to pin down, the record is clear in placing onset no later than “a few days” post-vaccination and definitely less than seven days post-vaccination.

Although onset within forty-eight hours is required by the Vaccine Injury Table, onset in a cause-in-fact claim does not need to occur precisely within forty-eight hours. In *Jewell v. Secretary of Health & Human Services*, former Chief Special Master Dorsey found that although petitioner was unable to establish onset within forty-eight hours of vaccination, the onset of her shoulder injury within seventy-two hours was a “medically appropriate temporal relationship.” *Jewell v. Sec’y of Health & Human Servs.*, No. 16-0670V, 2017 WL 7259139, at *3 (Fed. Cl. Spec. Mstr. Aug. 4, 2017). Further, the Federal Circuit has counseled that special masters should not set “hard and fast deadlines” when evaluating the appropriate timeframe for onset after vaccination. *Paluck v. Sec’y of Health & Human Servs.*, 786 F.3d 1373, 1384 (Fed. Cir. 2015). Accordingly, petitioner has preponderately demonstrated that her musculoskeletal shoulder symptoms began within a timeframe for which it is medically acceptable to infer causation-in-fact.

iv. Factors Unrelated to Vaccination

Pursuant to the Vaccine Act, once petitioner has met her *prima facie* burden of establishing a cause-in-fact claim, respondent may still prove the condition is “due to factors unrelated to the administration of the vaccine describe in the petition.” § 300aa-13(a)(1)(B). As discussed above, respondent has not persuasively established that petitioner’s presentation can be entirely explained by AC joint arthritis or cervical radiculopathy. Therefore, respondent cannot meet his burden to show that petitioner’s condition is due to factors unrelated to the flu vaccine she received on October 12, 2016.

I. **Conclusion**

For all the reasons discussed above, after weighing the evidence of record within the context of the Vaccine Program, I find by preponderant evidence that petitioner’s shoulder injury was caused-in-fact by the flu vaccine she received on October 12, 2016. A separate damages order will be issued.

IT IS SO ORDERED.

s/Daniel T. Horner
Daniel T. Horner
Special Master